DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 2 8 2005

Guidant Endovascular Solutions
c/o Ms. Julia Anastas
Advisor, Regulatory Affairs
3200 Lakeside Drive
Santa Clara, CA 95054

Re: K042218
RX ACCUNET™ Embolic Protection System
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: NTE
Dated: August 3, 2004
Received: August 5, 2004

Dear Ms. Anastas:

This letter corrects our substantially equivalent letter of August 31, 2004.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Donna R. Richmond

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K042218

Device Name:

ACCUNET™ Embolic Protection System
RX ACCUNET™ Embolic Protection System

Indications For Use:

The ACCUNET™ Embolic Protection System and the RX ACCUNET™ Embolic Protection System are indicated for use as a guidewire and embolic protection system to contain and remove embolic material (thrombus/debris) while performing angioplasty and stenting procedures in carotid arteries. The diameter of the artery at the site of filter basket placement should be between 3.25 mm and 7.0 mm.

Prescription Use __X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K042218

GUIDANT

510(k) SUMMARY

The 510(k) Summary is submitted in accordance with 21 CFR Part 807, Section 807.92

Submitter's Name:	Guidant Corporation Endovascular Solutions
Submitter's Address:	3200 Lakeside Drive Santa Clara, CA 95052
Telephone: **Fax**:	(408) 845-3000 (408) 845-2304
Contact Person:	Laraine Pangelina, Principal Regulatory Affairs Associate
Date Prepared:	August 3, 2004
Device Trade Name:	ACCUNET™ Embolic Protection System RX ACCUNET™ Embolic Protection System
Device Common Name:	Embolic Protection Device
Device Class:	Class II
CFR Classification/Name:	21 CFR 870.1250, Percutaneous Catheter

Identification of Predicate Device:

The ACCUNET™ and RX ACCUNET™ Embolic Protection Systems are substantially equivalent to the Boston Scientific FilterWire EX™ Embolic Protection System (K023691).

Device Description:

The ACCUNET™ Embolic Protection System is an over-the-wire, filtration-type, embolic protection system, filtering distal to the interventional site. The ACCUNET™ System is delivered via a Delivery Sheath with a flexible tip coil that facilitates movement of the Sheath through tortuous anatomy. Once the Guide Wire is across the lesion, the Filter Basket is expanded in the artery lumen by removing the Delivery Sheath. The Filter Basket is recovered using the Recovery System, retaining any potential emboli collected during the procedure. The system and any captured embolic particles are then removed through the guiding catheter or sheath.

Like the ACCUNET™ Embolic Protection System, the RX ACCUNET™ Embolic Protection System is a filtration type embolic protection device, filtering distal to the interventional site. The RX ACCUNET™ Embolic Protection System is delivered via a Delivery Sheath with a flexible tip coil that facilitates movement of the Sheath through tortuous anatomy. Once across the lesion, the Filter Basket is expanded in the arterial lumen by peeling the Delivery Sheath from the Guide Wire using the torque device and peel-away adapter. At the conclusion of the interventional procedure, the Filter Basket is collapsed inside the Recovery Catheter. Once collapsed, the entire system is removed as a single unit.

Indication for Use:

The ACCUNET™ Embolic Protection System and the RX ACCUNET™ Embolic Protection System are indicated for use as a guidewire and embolic protection system to contain and remove embolic material (thrombus/debris) while performing angioplasty and stenting procedures in carotid arteries. The diameter of the artery at the site of filter basket placement should be between 3.25 mm and 7.0 mm.

Technological Characteristics:

The ACCUNET™ and RX ACCUNET™ Embolic Protection Systems are substantially equivalent to the Boston Scientific FilterWire EX™ Embolic Protection System (K023691) with regard to device design, principals of operation, materials, and indications for use. The following design attributes are the same or similar for both subject devices and the predicate device:

- Over the wire and/or rapid exchange systems
- Filter based technology
- Polyurethane filter membrane
- Nitinol filter/basket component
- Compatibility with .014" guidewires
- Compatibility with 6F guide catheters
- Available in 190 and/or 300 cm lengths
- Accommodates similar vessel sizes
- Radiopaque guidewire tips and/or delivery sheath tips
- Radiopaque markers on filter

Any new issues of safety or efficacy were addressed through extensive clinical testing and pre-clinical evaluation including functional, animal, biocompatibility, packaging and shelf-life testing.

Performance Data:

In vitro testing of the ACCUNET™ and RX ACCUNET™ Embolic Protection Systems included biocompatibility, sterilization, packaging and shelf-life, and product performance testing. *In vitro* bench testing was developed based on the device risk assessment and is consistent with *Guidance for the Submission of Research and Marketing Applications for Interventional Cardiology Devices: Intravascular Stents* US FDA May 1995, and the applicable ASTM Standards. The relevant tests outlined in the guidance were conducted to demonstrate the *in vitro* safety and effectiveness of these devices.

The ACCUNET™ and RX ACCUNET™ Embolic Protection Systems were subjected to a series of acute and chronic animal studies in conjunction with the ACCULINK™ and RX ACCULINK™ Carotid Stent Systems. The intent of the studies was to demonstrate acceptable functional performance of the subject devices in an *in vivo* setting and to ensure that the devices do not cause untoward hemodynamic vascular or other biological (e.g. thrombotic events, etc.) responses. All studies were performed in the non-atherosclerotic swine model in accordance with the FDA Guidance for the *Submission of Research and Marketing Applications for Interventional Cardiology Devices dated May 1994*. All studies were conducted in accordance with Good Laboratory Practices (GLP) per 21 CFR § 58.

The ACCULINK™ for Revascularization of Carotids in High Risk Patients (ARCHeR) Clinical Trials were a series of prospective, non-randomized, multi-center, single-arm clinical trials. These trials were performed to demonstrate the safety and efficacy of the ACCULINK™ and RX ACCULINK™ Carotid Stent Systems and ACCUNET™ and RX ACCUNET™ Embolic Protection Systems when used to treat high-risk surgical and non-surgical symptomatic (≥50% stenosis) and asymptomatic (≥80% stenosis) subjects with disease

in the internal carotid artery. A total of 657 patients were enrolled at 45 clinical sites in the United States and five sites outside of the United States.

The ARCHeR 1 and ARCHeR 2 trials were designed to show equivalence (non-inferiority) between carotid stenting and an historical control, based on the standard of care. The historical control was established based on a review of the current literature on carotid endarterectomy and medical therapy and is defined as the weighted historical control (WHC). The WHC rate at one year has been calculated for both ARCHeR 1 and 2 to be 14.5%. The ARCHeR 3 trial was designed to demonstrate equivalence (non-inferiority) of the safety and performance of the rapid exchange RX ACCULINK™ and RX ACCUNET™ to results observed in the ARCHeR 2 trial for the OTW ACCULINK™ and ACCUNET™ based on 30-day results.

With respect to ARCHeR 1 and ARCHeR 2, the upper confidence limits for primary endpoint rates were well below the 14.5% WHC. The 30-day composite primary endpoint rates in ARCHeR 3 and ARCHeR 2 were 8.28% and 8.63%, respectively. The upper bound of the 95% confidence interval of the difference is 4.75%, which is less than the delta of 8% (p=0.005). Thus, results from ARCHeR 3 are determined to be equivalent to that of ARCHeR 2.

The differences observed in primary endpoint event rates between the three trials is not statistically significant and supports the safety and effectiveness of the ACCULINK™ carotid stent used with or without the ACCUNET™ embolic protection device.